ing considered on each criterion in the preference structure; 4) Normalize and average the preferences for each drug agent; 5) Create a statistic that indicates consistency in quantifying the preferences; 6) Determine the preference of each criterion relative to every other criterion in the preference structure (normalize, average, and check consistency); 7) Determine summary preference "score" for each drug agent; 8) Choose the drug agent having the greatest summary preference.
RESULTS: The optimal drug identified by the AHP was the same drug agent identified by the Formulary Steering Committee for inclusion in the formulary. However, the AHP achieved this result with a comparable reduction in inconsistency, greater efficiency and the ability to perform a sensitivity analysis of the outcome.
CONCLUSIONS: The analytical hierarchy process can be used to successfully identify appropriate drug agents for formulary placement in managed care settings. Use of this method allows formulary members to quantify their subjective preferences among competing drug agents.

PDR6

EVALUATION OF THE STRUCTURAL VALIDITY OF THE SF-12

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OBJECTIVE: The purpose of the present study was to validate the structural model of the SF-12 with data from the 1990 National Survey of Functional Health Status (NHS).
METHODS: We used Confirmatory Factor Analytic (CFA) to evaluate the structure of the MOS SF-12. CFA is ideally suited for examining self-report survey tools, in that the proposed structural characteristics are statistically evaluated by comparing the estimated population covariance matrix, estimated from the proposed parameters, to the sample covariance matrix.
RESULTS: There was substantial support for the hypothesized structure of the SF-12; however, it was not a statistically adequate fit (r^2 = 1672.27; fit indices were well below 0.9 [CFI = 0.85]). The model was significantly improved by adding a covariance path between Physical Health and Mental Health, adding an additional link between General Mental Health and Physical Health, and the addition of two covariances among the item errors. This revised structure represented a good fit to the data (r^2 = 338.26; fit indices were well above 0.9 [CFI = 0.97]). This suggests that there are some commonalties between self-reported Physical and Mental Health. This was supported by the strong correlation between Physical Health and Mental Health (r = 0.838; 70% shared variance).
CONCLUSION: While there was some support for the hypothesized structure, there was substantial evidence to support the dependencies between Physical and Mental Health. These findings are very similar to our previous work with the SF-36 that suggests that a substantial portion of these two constructs, Physical and Mental Health, reflect a common construct. The SF-12 appears to be relatively free of correlated errors, unlike the SF-36, and may have fewer problems with systematic measurement error or idiosyncratic interpretation of item content.

PDR7

DEVELOPING A QUALITY ASSESSMENT SCORING SYSTEM FOR ECONOMIC EVALUATIONS

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OBJECTIVE: In recent years, a number of primers, standards, and guidelines have appeared in the pursuit of promoting "good practice" and improving the overall quality of economic evaluations. However, none of these contain the logical next step: a scoring system that evaluates and summarizes the quality of the studies. This research investigates whether a scoring system can be developed for published economic evaluations, and discusses how such a system can assist in clearly identifying studies of a better quality, which in turn would provide the evidence to allow priorities to be set in a more explicit manner. We construct a scoring system based on an adaptation of the BMJ Working Party 35-point checklist, and illustrate its application to a case study of schizophrenia.
METHODS: A comprehensive literature search was conducted for the period 1966–1997. The inclusion criteria were: 1) the study considered both the costs, and cost or health consequences of alternative health programs for schizophrenia; 2) the study was published in English; 3) the majority (i.e., >50%) of the patients sampled had a diagnosis of schizophrenia or related psychoses. The studies were scored according to the maximum total which could be achieved for each study. Selected items (e.g., perspective) were given more weighting according to their importance as determined by a recent survey of health economists.
RESULTS: Thirty studies met the inclusion criteria (17 US, 7 UK, 6 elsewhere). The studies either considered alternative methods of service delivery or the use of novel antipsychotic drugs (e.g., clozapine or risperidone). The quality scores ranged from 43–88%.
CONCLUSIONS: It is shown that our scoring approach may be one reasonable method of summarising methodological quality. Further research needs to be performed on the development of economic quality scoring methods and the link between the quality of economic information to their effects on decision-making.

PDR8

MINIMAL STANDARDS FOR THE VALIDATION OF QUALITY OF LIFE INSTRUMENTS USED IN CLINICAL TRIALS

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OBJECTIVES: Quality of life (QoL) is being increasingly used as a secondary endpoint in clinical trials. The accurate and precise measurement of QoL requires rigorous scientific attention to the design and validation of questionnaires. The aim of the present study is to review the available regulatory and medical literature and to suggest minimal standards for the validation of QoL instruments.
METHODS: Existing FDA and EMEA guidelines were reviewed. A Medline search strategy was developed to identify and retrieve relevant publications.
RESULTS: There are currently no regulatory guidelines from either the FDA or EMEA regarding validation of QoL instruments. The search strategy identified 238 articles on instrument validation and 22 review articles on validation methodologies. There is consensus in the literature that QoL assessment must be formally validated in order to be acceptable as scientific evidence of intervention effectiveness. Minimal validation criteria include: 1) a clear definition of QoL relevant to the studied population, 2) documentation of scientific methods used to develop questionnaire instrument(s), 3) demonstration of the performance of the instrument(s) in terms of acceptability, validity, and responsiveness, and 4) documentation of statistical methods used to derive scales, domains, and other constructs.
CONCLUSIONS: A validation study should be performed prior to incorporating QoL instruments into clinical trials. Results of these studies should be published in the medical literature. A validation checklist is proposed to assist regulatory bodies in evaluating the quality of QoL instruments used to support regulatory applications.

PDR9

CLINICAL EPIDEMIOLOGY PRINCIPLES OF AND THE COST OF DRUG TRIALS

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Pharmaceutical manufacturers are spending more than 10% of their annual gross income for research and development. Pre-clinical studies take 20% of these expenditures and clinical phases take 40%. But only 5% of the substances that have passed the pre-clinical phase successfully will pass the four clinical phases and be approved for usage. Such an outcome explains the low sensitivity and selectivity of test-systems using the laboratory animal as a model of human. These systems are based on widespread theory of the phylogenetic species continuity concept which propose that human and animals have the same sensitivity to the therapeutic and toxic action of drugs. The biochemical species stability concept is less known and postulates the essential interspecies and intraspecies variability on a biochemical level. According to this theory, human material (cell cultures and tissues) should be used as a test-system for drug testing. Clinical epidemiology is the new fast growth discipline which gives evidence for using methods of therapy or diagnostics. It has routine procedures for the quantitative estimation of test-systems and characterizes them by sensitivity, selectivity, and validity. These procedures allow to discard low effective test-systems. Principles of clinical epidemiology can increase successful trials and diminish costs.

PDR10

PREDICTING MARKET SHARES FOR NEW PHARMCEUTICAL PRODUCTS USING STATED PREFERENCES

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OBJECTIVE: The purpose of this research is to develop a decision model for evaluating the impact of information regarding alternative treatments, toxicity, efficacy, delivery method, and cost on demand for unique compounds.
METHODS: This paper characterizes the relationship between multi-attribute utility theory and health-state preferences. Health outcomes arising from pharmaceutical interventions are viewed as multiattribute commodities. Presenters describe a method for reliable, utility-theoretic quantification of health-state preferences. This procedure requires estimating utility weights from stated-preference (SP) data. Including health cost as an SP attribute facilitates conversion of marginal utilities to marginal dollar values to explicitly account for cost in determining market share. Additionally, various utility specifications and simplifying assumptions are described. Finally, a rule for simulating aggregate choice behavior over time is presented. The prediction rule employed draws upon random utility maximization with adaptive expectations. This method addresses the probabilistic nature of the choice process by inclusion of a residual term representing the effect of unobserved factors on perceived utility. Expectation updating deals with imperfect information about product attributes such as efficacy and side effects by allowing learning to take place over successive drug administrations.
RESULTS: A numerical example considering migraine medications demonstrates the capability of the decision model. In this example, a general, preference-based form for health-related utility facilitates direct estimation of health attribute utility weights arising from pharmaceutical consumption. Manipulating pharmaceutical attributes in a random utility framework simulates choice probabilities. Repeatedly simulating choice probabilities with attribute expectation updating provides market penetration estimates for unique compounds over time.
CONCLUSIONS: Combining stated preference survey techniques with random utility and adaptive expectations provides a unique and realistic method for predicting demand for novel compounds.